CALIGRA MANAGEMENT, LLC
1201 ELKFORD LANE
JUSTIN, TX 76247
817-726-3015 (phone)
888-501-0299 (fax)

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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Lyrica medication

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Pain Management Physician

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a female employed with XX in XX as a XX who suffered from chronic low back pain.

On XX/XX/XX, a urine drug screen (UDS) was completed at XX. Zolpidem and hydrocodone were not detected, which was inconsistent with the prescription. The test was positive for pregabalin, which was consistent.

On X/X/XX, the patient was evaluated for follow-up of her low back pain. She presented with complaints of severe low back pain rated at 7/10. She reported therapy had helped. She was currently off work. Medical history was significant for back symptoms, hysterectomy, allergies, and hepatitis A. Medications included Lyrica, Robaxin, Ambien, naproxen, scar gel, Cymbalta and Excedrin. Examination revealed the patient was in moderate distress with decreased range of motion (ROM), tenderness and muscle spasm of the back. The low back pain radiated to the leg and the patient reported sleep disruption secondary to pain. She was diagnosed with acute lumbar myofascial strain, lumbar post laminectomy and lumbar radiculitis, placed on light duty and referred to Pain Management. She was discharged on Cymbalta, Robaxin, Lyrica and Ambien.

On XX/XX/XX, XX evaluated the patient for her low back pain. She had been injured at work in XXXX, which had occurred with twisting and lifting. She had undergone physical therapy (PT) and multiple injections prior to having an L4-S1 fusion with hardware in XXXX and removal of hardware in XXXX. Prior to her back surgery, she had a Boston Scientific spinal cord stimulator implanted, which had not worked in over a year. She was currently in a chronic pain program at XX and managed her pain with Lyrica, Robaxin and Vicoprofen. She reported being out of the medications for almost a month. CT myelogram in XX/XXXX had noted a 4-mm disc bulge at L3-L4 contacting the left L3 and both L4 nerve roots. The patient presented with constant, sharp low back pain radiating into the right foot, worse with bending, walking, sitting and standing. She reported that rest, Epsom salt baths, heat and medication helped. Her pain level was 8/10. She admitted to numbness and weakness in the right leg and denied bowel/bladder dysfunction. Examination revealed diffuse lower paraspinal tenderness, bilateral sacroiliac (SI) joint tenderness, decreased flexion and an implantable pulse generator (IPG) in the left flank. Sensory was significant for decreased pinprick in S1 on the right. XX assessed other chronic postprocedural pain, radiculopathy in the lumbar region and postlaminectomy syndrome and opined that the patient was unlikely to improve with injections. He advised evaluation of the spinal cord stimulator (SCS) by the Boston representative, prescribed vicoprofen and ordered a UDS.

On XX/X/XX, XX documented a Letter of Medical Necessity after reviewing previous medical records and documented diagnoses of lumbar disc displacement, lumbar postlaminectomy, lumbar sprain and lumbar radiculitis. It was noted that the patient had completed all lower levels of medical treatment including acute supervised physical medicine, home exercise therapy instruction and had also been given therapeutic supplies (e.g. lumbar myofascial foam roll, core stability ball, lumbar brace) and had a trial course of medication and TENS electrical stimulation unit (which was denied by the carrier). She had also received nerve blocks with trigger point injections, Toradol pain injections, and lumbar epidural steroid injections (LESI). She had undergone spinal stimulator implantation followed by postoperative physical medicine. She then underwent spinal surgery and later, hardware removal. She continued to suffer from her work injury medical condition of XX/XX/XX, and was being referred to a multidisciplinary chronic pain management program with emphasis on functional restoration and treatment of psychological return to work barriers, and pain medication reduction. He documented that the patient required the following medications to allow her to continue the PAIN MANAGEMENT PROGRAM and improve activities of daily living (ADLs) and the medications were medically necessary: Robaxin, Lyrica, Cymbalta and Ambien. The patient would be titrated upon completion of a functional restoration program for pain management program. The goal was to reduce medication consumption usage on a daily basis including reduction of Ambien and Lyrica.

On XX/XX/XX, XX placed a request for preauthorization of revision of the SCS.

On XX/XX/XX, XX completed a peer review and opined that Lyrica was not medically necessary. Rationale: "*I am unable to support this request. It appears that the claimant has been on Lyrica for some time now and there is no documentation as to how this has impacted her neuropathic pain.*

Without such documentation, I am unable to support ongoing use of this medication. I am unable to support the use of this medication. Therefore, LYRICA/CAP 200 MG Day Supply: 30 Qty: 90 Refills: 00 is not medically necessary. However, due to the nature of this drug, weaning is recommended."

On XX/XX/XX, XX denied the specific request of Lyrica Cap 200 mg.

On XX/XX/XX, XX completed a peer review and denied the requested services of Lyrica, the following rationale: "*This medication is supported by ODG for the therapy of neuropathically mediated pain which is present here. However, it is denied as there is no functional benefit documented with its use. Despite using a maximal dose of Lyrica, Cymbalta, and the SCS, the claimant continues to have a pain score rated at a 6/10. There is no mention in the notes that Lyrica is providing any specific benefit or relief as well. Therefore, the request for POS LYRICA CAP 200MG Day Supply: 30 Qty: 90 Refills: 00 RxDate XX/XX/XX is not medically necessary. However due to the nature of the medication weaning is recommended."*

On XX/XX/XX, per utilization review, XX upheld the denial.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Lyrica is an anticonvulsant medication. This medication is approved and supported for neuropathic pain by the ODG: Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. *Outcomes:* A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails.

After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. AEDs are associated with teratogenicity, so they must be used with caution in woman of childbearing age. Preconception counseling is recommended for anticonvulsants (due to reductions in the efficacy of birth control pills).

The documentation of pain relief includes the patient stating that the "medications" make the pain better. Due to the limited documentation of pain relief and no documentation in improvement in function, the request for Lyrica, per the ODG is denied. However, due to the

nature of the medication weaning is recommended.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES